

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of scar outcomes of incision of alar base resection inside alar-facial groove and 2 mm above this groove in rhinoplasty patients: a randomized clinical trial

Protocol summary

Study aim

Selecting the best place to do the incision of alar base resection in rhinoplasty patients who have wide alar base

Design

Two arm, parallel group, randomized double-blinded clinical trial; phase 3 on 60 patients. Block randomization using the table of random numbers is used for random allocation.

Settings and conduct

Place: ENT ward, Imam Khomeini hospital, Tehran
Population: Rhinoplasty patients with a wide alar base
Blinding: double-blinded Method of blinding: Individuals undergoing rhinoplasty will not be aware of the surgical technique for their alar base resection. In addition, the person who analyzes the data and the expert who assesses the scar outcome will also be blind to the surgical method performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: individuals seeking rhinoplasty who are candidates for alar base resection. Non-inclusion criteria: history of alar scar; systemic skin diseases and collagen-vascular disorders; congenital alar deformities; repeated alar surgeries

Intervention groups

In the intervention group, the incision for alar base resection is placed in 2mm above the alar-facial groove, and in the control group, the incision for alar base resection is placed inside alar-facial groove. Other surgical techniques in all stages are similar in both groups. Skin incisions are sutured with 6-0 nylon thread.

Main outcome variables

Alar base resection scar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220420054597N1**

Registration date: **2022-07-18, 1401/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-18, 1401/04/27**

Update count: **0**

Registration date

2022-07-18, 1401/04/27

Registrant information

Name

Goli Golpayegani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 9225

Email address

golpayegani.goli@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of scar outcomes of incision of alar base resection inside alar-facial groove and 2 mm above this

groove in rhinoplasty patients: a randomized clinical trial

Public title
Comparison of scar outcome in different techniques of alar base resection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
individuals seeking rhinoplasty who are candidates for alar base resection due to their wide nasal base
Exclusion criteria:
History of scar Systemic skin diseases and collagen-vascular disorders Congenital alar deformities Repeated Alar surgery

Age
From **17 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Ten blocks, each consisting of 6 patients, will be formed. In each block, 3 patients are assigned to the intervention group and the remaining 3 patients are assigned to the control group. Randomization in each block will be obtained using the table of random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Individuals undergoing rhinoplasty will not be aware of the surgical technique for their alar base resection. In addition, the person who analyzes the data and the expert who assesses the scar outcome will also be blind to the surgical method performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical

Sciences

Street address
Tehran University of Medical Sciences, Poorsina Street, Qods Street, Enghelab Street, Tehran

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2022-03-14, 1400/12/23

Ethics committee reference number
IR.TUMS.AMIRALAM.REC.1400.064

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

Z41.1

ICD-10 code description

Encounter for cosmetic surgery

Primary outcomes

1

Description

Scar score in Visual Analogue Scale

Timepoint

Before, 1 month, 3 months, and 6 months after the intervention

Method of measurement

Visual Analogue Scale

2

Description

Scar score in Stony Brook Scar Evaluation Scale

Timepoint

Before, 1 month, 3 months, and 6 months after the intervention

Method of measurement

Stony Brook Scar Evaluation Scale

Secondary outcomes

1

Description

Surgical complications

Timepoint

before, 1 month, 3 months, and 6 months after the intervention

Method of measurement

Surgeon's report

Intervention groups

1

Description

control group: alar base resection incision in alar-facial groove

Category

Treatment - Surgery

2

Description

Intervention group: alar base resection incision in 2mm above alar-facial groove

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Goli Golpayegani

Street address

Qarib Street

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

6th floor, Central building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

<https://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

1400-3-112-55199

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Goli Golpayegani

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Age, gender, and scar score of the patients will be shared after de-identification

When the data will become available and for how long

From 6 months after publication upon reasonable request thereafter.

To whom data/document is available

available for people working in academic institutions

Under which criteria data/document could be used

The corresponding author decides on which analyses are permitted.

From where data/document is obtainable

Golpayegani.goli@gmail.com Goli Golpayegani

What processes are involved for a request to access data/document

the applicant's details, the proposal for which the data is requested, and the academic institution the applicant is working for.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Goli Golpayegani

Position

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Latest degree

Specialist

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